

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

**REDACTED PUBLIC VERSION
FILED MARCH 4, 2024**

C.A. No. 21-691-GBW

[REDACTED]

[REDACTED]

**REDACTED PUBLIC VERSION
FILED MARCH 4, 2024**

C.A. No. 21-1138-GBW

[REDACTED]

[REDACTED]

**REDACTED PUBLIC VERSION
FILED MARCH 4, 2024**

C.A. No. 21-1594-GBW

[REDACTED]

[REDACTED]

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS FROM DANIEL M.
SILVER REGARDING DEFENDANT'S OPPOSITION TO PLAINTIFFS'
FEBRUARY 24, 2024 LETTER ON EVIDENTIARY DISPUTES**

Dear Judge Williams,

A. Jazz’s arguments improperly seek summary judgment and/or MIL rehearing

Jazz elected not to move for summary judgment on any inventorship issue. Jazz then filed MIL No. 2 seeking to preclude Avadel from arguing inventorship at trial. This Court denied the motion, including because “the elimination of a legal issue is the proper function of a summary judgment motion—not a motion *in limine*.” D.I. 540 at 5. Now, after a jury has been empaneled, Jazz again asks to preclude Avadel from **presenting a defense**, not just evaluating what evidence is relevant to the claims that **remain** in the case, as is the proper function of a letter brief. That request should be denied as another improper and belated attempt by Jazz to obtain dispositive relief through a motion *in limine*. *Id.* Indeed, Jazz is effectively requesting rehearing on MIL No. 2, where Jazz tried and failed to prevent Avadel from arguing inventorship.

Jazz’s claim that the parties have been proceeding as though Avadel had given up portions of its inventorship defense is wrong. That did not happen. The **only** order addressing Avadel’s inventorship defense is the order **denying** Jazz’s MIL seeking to eliminate that defense. The parties had an agreement on narrowing defenses; Avadel elected “Improper Inventorship” with no restrictions. Ex. 1. The order denying consolidation with the trade secret case did not limit Avadel’s ability to present evidence in support of its defenses in this case. Rather, the Court found “that the patent cases and the trade secrets case do not share enough common issues of law to justify consolidation under the circumstances.” D.I. 381. Jazz claims that Avadel recently failed to dispute Jazz’s point, but the opposite is true. Jazz asserted, in MIL 2, that Avadel’s inventorship defense was limited. Jazz Ltr. at 1 (citing D.I. 535-6B Op. at 3.n2.) Avadel opposed that motion (including fn2) in full and took issue with the suggestion that Jazz’s motion could “affect Avadel’s ability to have its former employees explain when they invented LUMRYZ.” D.I. 535-6B Opp. MIL 2 at 1, 3. The Court denied Jazz’s motion. Avadel’s inventorship defense is live in this case, in full, and Avadel’s former employees will explain when and how they invented LUMRYZ.

Jazz’s letter is also an improper request for rehearing on MIL No. 3. In MIL No. 3, Jazz argued, as it does here, that evidence on the same “subject matter” of another case should be excluded. Avadel opposed. “Avadel also contends that Jazz’s motion is overly broad because it seeks to exclude evidence or argument on the ‘subject matter’ of other litigation between the parties when that subject matter could also be relevant to this action.” D.I. 540 at 7. The Court’s ruling permits use of such overlapping proof, as it granted Jazz’s motion **in part**, and precluded Avadel from offering in this case only evidence that is “**solely relevant**” to another case. *Id.* That Avadel sought consolidation due to “**common**” issues of fact shows that such proof is not “**solely**” relevant to the other action.

Jazz’s motion concedes that some facts and documents are relevant to proving **both** improper inventorship (an issue in this case) **and** that Jazz misappropriated trade secrets (an issue to be decided later). Indeed, when Avadel sought to prevent Mr. Stoll from testifying, Jazz argued successfully that his testimony was relevant to both inequitable conduct and improper inventorship. D.I. 540 at 10-12. Jazz’s letter notes one place where Avadel made that clear: In its Invalidity Contentions in **this** case, Avadel explained how evidence recounted in the trade secrets complaint **also** provided evidentiary support for Avadel’s argument here that Jazz’s patents are invalid for failing to name true inventors, namely, Avadel’s former employees whose work

Jazz copied. Jazz Ex. A at 134-35. A mountain of documents provide evidentiary support for that conclusion. For example, DTX-0250, a 2014 Jazz document used in depositions in this case, shows that Jazz thought that Avadel/Flamel was going down the wrong path by using beads. Ex. 2 at 7-8. That is not the statement of an inventor who has already invented (or described or enabled) a bead-based formulation, and the document supports the contention that Jazz did not possess the invention it would later claim and that Jazz was closely following Avadel's work, which is probative that Jazz ultimately copied that work. That evidence all supports Avadel's unified single defense of improper inventorship. Contrary to Jazz's letter, Avadel does not have two different inventorship defenses. The "TS-based inventorship theory" that Jazz points to in Avadel's Invalidity Contentions appears in a section titled "Response to Jazz on Invalidity of the Sustained Release Patents for *Improper Inventorship*" and is not a separate defense; that section makes clear that it is cross-referencing the "factual circumstances," as is entirely appropriate. See Jazz Ex. A at 132. In other words, Avadel will not be asking this jury to decide trade secret issues; Avadel will be asking the jury to decide patent invalidity based on improper inventorship. Avadel is not pursuing a backdoor trade secrets claim. Those claims will be tried in 2025.

Jazz's request is also an attempt to evade this Court's procedures. Jazz mentions individual documents but fails utterly to address them in a way that would allow for the evidentiary rulings that Jazz said it was seeking. Among other problems, many of the documents listed in the letter are relevant to other issues in this case, e.g., damages or written description. See, e.g., *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 2016 WL 6901742, at *2 (D. Del. Nov. 22, 2016) (evidence similar to that here relevant to written description). Finally, Jazz's assertion that "Avadel would not be prejudiced *at all*" (Jazz Ltr. at 2) is unquestionably wrong. Jazz is attempting to deprive Avadel of a core defense at the start of trial.

B. There is no previously undisclosed inventorship defense

Avadel is not arguing that its former employees invented the claimed inventions in 2004. There is no undisclosed inventorship theory. Had Jazz asked that basic question during the parties' meet and confer, Avadel could have confirmed that for Jazz, but Jazz did not ask.¹

DTX-1694—the subject of Jazz's letter—is an Avadel patent application, No. 10/826,690 (Ex. 3) that issued as U.S. Patent No. 8,101,209 on its proprietary Micropump II platform, which Avadel's former employees used in their formulation efforts ultimately leading to LUMRYZ. That patent was produced in discovery in this case by Jazz (Ex. 4) and was otherwise referenced in many other documents including documents produced by Jazz. Avadel is fine using the issued patent in place of DTX-1694. But it is not even remotely a new development that Avadel's Micropump II technology is relevant to this case.

For example, when Jazz deposed Dr. Herve Guillard (an inventor of LUMRYZ) in October 2022, Jazz examined him regarding JTX-230, which notes how Mr. Guillard relied on "Flamel's Micropump II patents (US8101209)" to develop LUMRYZ. Ex. 5 at 33. Micropump II came up numerous other times in testimony and documents during the deposition. E.g., Ex 6 at 28; *id.* at

¹ Given that Avadel is not making any new argument, Jazz's footnote 1 is irrelevant. It is also incomplete. Post-AIA patents are still subject to the inventorship requirement. See *Belcher Pharms., LLC v. Hospira, Inc.*, 2019 WL 2503159, at *1 n.1 (D. Del. June 5, 2019).

29. Thus, “Micropump II” has long been in the case and helps explain how LUMRYZ works and how it was developed. This is fully consistent with Avadel’s Rule 26(a) disclosures, in which Dr. Guillard was listed as having knowledge regarding the “technical information regarding the development of [FT218].” Jazz Ltr. at 2. Jazz’s Saturday disclosure of its opening demonstratives shows yet another reason why Avadel’s Micropump II patent is relevant—Jazz wants to accuse Dr. Guillard of copying *from Jazz*. Ex. 7 at 34. Instead, Dr. Guillard leveraged existing *Avadel* technology, including the Micropump II technology, to develop LUMRYZ.

C. Jazz’s MIL No. 1 does not preclude Avadel’s use of documents relevant to many issues

In its order, “the Court grant[ed] Jazz’s motion to preclude Dr. Charman from testifying that the Asserted Claims are invalid for lack of enablement or written description” for an itemized list of reasons. D.I. 540 at 4. The Court’s Order did *not* wholesale exclude documents relevant to a range of issues. Avadel will not be making the arguments that were excluded by MIL No. 1. But that does not render all of Jazz’s failures irrelevant. *See Idenix Pharms.*, 2016 WL 6901742, at *2 (denying MIL because “extent to which the purported ‘failures’ arose in connection with ‘following the patent specification’ is a disputed factual issue”). Indeed, Jazz’s opening slides show that it intends to portray itself as the “Industry Leader in Sleep Medicine.” Ex. 7 at 15. Where, as here, “[t]he parties hotly contest which of them is the innovator,” courts favor allowing the parties “to present evidence to support their view of that controversy.” *Idenix Pharms.*, 2016 WL 6901742 at *3.

In addition, every document on Jazz’s list contains competent evidence on multiple issues that remain live in this case. In this short space, Avadel can discuss only a few. DTX-675 (Ex. 8) is an email from Jazz’s named inventor from 2019 in which he states “As you probably know, we got into once nightly only because Flamel went there first so we had to follow. I still expect it to be a dog in terms of commercial opportunity.” *Id.* That email is relevant to at least inventorship, written description, and damages, and directly rebuts Jazz’s story that Avadel followed Jazz. DTX-236 (Ex. 9) is a Jazz review of some of its research, showing skepticism and copying, and that Jazz’s research underlying the ’488 patent (PLE-2 items) is limited to tablets (contrary to what Jazz claims). Ex. 9 at 7. It goes to at least inventorship, written description, and enablement, and directly refutes claims made by Jazz in its opening demonstratives. Had Jazz followed the Court’s evidentiary procedures, Avadel would have the ability to explain why the remaining documents equally are relevant to many other issues in this case; at a minimum, the Court should deny Jazz’s motion to permit that to occur.

D. The Avadel inventors should not be forced to testify in French at trial

The Court should permit Drs. Guillard and Mégret to testify in English. Their English is imperfect but conversant, and translation places significant time constraints on an already tight trial timeline and can make it harder for the jury to understand and assess the credibility of their testimony. Jazz cites to no case law that states that a witness must testify at trial in the same language they testified in during their deposition, and least one court in this District has declined to force witnesses to testify in a particular language. *See Ex. 10 (Ateliers De La Haute-Garonne v. Broetje Automation, USA Inc., C.A. No. 1:09-cv-00598-LPS, D.I. 405 at 33 (D. Del. Mar. 21, 2014)); Ex. 11 (Id., D.I. 334 at 98) (approving regime where party had “every intent” to have witness speak in English but would have an “interpreter standing nearby” in case of any issues).*

Respectfully submitted,

/s/ Daniel M. Silver

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cc: All counsel of record (via CM/ECF and E-Mail)